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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,057	11/21/2000	Michael Brines	10165-010-999	5119

7590 10/26/2004  
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New York City, NY 10036-2711

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/717,057

**Applicant(s)**

BRINES ET AL.

**Examiner**

Regina M. DeBerry

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-7 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-7 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 August 2004 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Status of Application, Amendments and/or Claims***

The amendment filed 16 August 2004 has been entered in full.

Claims 1, 8, 10 and 11 were cancelled. Claims 2-7 and 9 are under examination.

The information disclosure statement (IDS) filed 16 August 2004 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

### **Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement**

Claims 2-7 and 9 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

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a method for enhancing the function of normal or **injured** excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a peripherally effective, non-toxic, excitable tissue enhancing amount of recombinant EPO, wherein said enhancing the function of excitable tissue results in the enhancement of associative learning or memory,

does not reasonably provide enablement for:

a method for enhancing the function of normal or **damaged** excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a peripherally effective, non-toxic, excitable tissue enhancing amount of recombinant EPO, wherein said enhancing the function of excitable tissue results in the enhancement of associative learning or memory.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at page 2 of the previous Office Action (05 April 2004).

Applicant cites the Examiner's rejection from the previous Office Actions (15 July 2003 and 05 April 2004). Applicant states that the Examiner indicated that the specification provides sufficient enabling disclosure for a method for enhancing the function of normal excitable tissue. Applicant states that the Examiner further indicated that the experimental data presented in Exhibit D correlates to methods for enhancing the function of abnormal tissue due to injury.

Applicant states that in order to address the Examiner's concerns and to facilitate allowance of claims, which the Examiner has asserted to be enabled by

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the specification, claim 1 has been amended to replace "abnormal" with "damaged". Applicant submits that the Examiner noted that the teachings of the specification coupled with the experimental data disclosed in the specification are sufficient to enable one of skill in the art to practice the instant invention and successfully enhance the function of normal or damage tissue.

Applicants' arguments have been fully considered and are deemed partly persuasive. The Examiner agrees with Applicant that the specification provides sufficient enabling disclosure for a method for enhancing the function of normal excitable tissue. However, "damaged excitable tissue" is the end result of many diseases and would still encompass conditions such as stroke, Alzheimer's disease, multiple sclerosis, etc. As was stated by the Examiner and reiterated by Applicant, the experimental data presented in Exhibit D correlates to methods for enhancing the function of abnormal tissue *due to injury*.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

### ***Conclusion***

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally

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rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

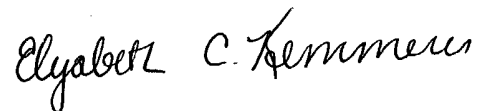
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RMD  
10/20/04



ELIZABETH KEMMERER  
PRIMARY EXAMINER